

RFA-DK-08-015: Chronic Kidney Disease Biomarker Discovery and Validation Consortium (U01).

1) Is my study population (transplant, US population) relevant to the problem of Chronic Kidney Disease?

The applicant should make the case that the chosen cohort[s] and assessed biomarkers are pertinent to CKD and the issues proposed in the RFA.

2) Will a Discovery Site or a Validation Site work independently?

We envision that the funded sites will work as a collaborative consortia/group. The final studies undertaken by the successful applicants will be determined after the grantees meet and work together to decide on joint and individual projects. The funded grantees will share ideas, samples, assay strategies, paradigms, etc and may develop common multi-assay nomograms/scoring systems. We envision that some of the projects will be limited to one Site (for example, Discovery sites).

3) Are studies using kidney transplantation patients responsive to the RFA?

Studies in transplant patients could adequately address the issues raised in the RFA, but it will be the responsibility of the applicant to make the case regarding relevance at the level of scientific and public health issues. The review group will have leeway in assessing the merits of any application involving transplants, and will advise the NIDDK on such matters. A focus on acute rejection, rather than chronic outcomes, would be viewed as relatively unresponsive to the RFA. Ultimately, NIDDK internal review and peer-review by external reviewers will determine the question of responsiveness. It is the responsibility of the applicant to make the case for transplant patients (the cohort[s] chosen, parameters assessed) as a CKD group pertinent to the issues proposed in the RFA.

4) Is knowledge of regulatory issues important for a Validation Site application?

A validation site should demonstrate knowledge regarding the scientific and regulatory issues related to validation and qualification, and will probably require extensive biostatistical and epidemiologic expertise. Demonstration of understanding of the components of the biomarker development process, including discovery, qualification, verification, assay characterization and optimization, and clinical validation will be important.

5) How many Validation and Validation and Coordination Sites will comprise the final consortium?

There will be only one Validation and Coordination site. The exact number of Discovery and Validation sites will depend on second level review considerations including the

quality of the science, availability of funds, and programmatic decisions regarding the focus, and expertise of participants in the final consortium.

6) Our proposed studies involve collaborations with NIDDK-funded studies and will use data and/or samples in the NIDDK repository. What are some of our responsibilities in submitting our application?

Please go to the websites cited in the RFA DK-08-015 announcement to determine study collaboration procedures and sample availability. For existing NIDDK-funded studies, consider directly contacting the Steering Committee to determine data availability. There should also be a letter demonstrating that the study collaboration procedures and sample availability are in keeping with the parent study. Applicants planning to use samples in repositories, or not in their possession, should demonstrate the following: 1) collaborative relationships, 2) sample availability, quality and characteristics, 3) sharing and access procedures, and 4) intellectual property rights, as appropriate, in the application. The plans must be adequate to achieve the study goals.